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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,335	12/12/2003	Doddabele L. Madhavi	BIO 2-016	3791

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Jerry K. Mueller, Jr.
Mueller and Smith, LPA
7700 Rivers Edge Drive
Columbus, OH 43235

EXAMINER	
FEDOWITZ, MATTHEW L	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,335	MADHAVI ET AL.	
	Examiner	Art Unit	
	Matthew L. Fedowitz	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/21/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 21 December 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the citations are incomplete and improper. The Information disclosure statement fails to include dates, pages and publication information. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing elements will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Response to Amendment

The Examiner is in receipt of applicant's response to the office action dated 29 October 2004. Applicant's response dated 21 December 2004, has the following affect:

Applicant's reply to the office action dated 21 December 2004 does not present any amendments to the pending claims. Claims 1-20 are pending and an action on the merits of said claims is set forth below. Further, applicant's response to the 35 U.S.C. 103(a) rejections for claims 4, 8, 14 and 18 obviates the rejection of record.

In view of applicant's disclosure of copending application 10/309,999 in the applicant's arguments, new grounds for rejection have been raised.

The declaration under 37 CFR 1.132 filed on 21 December 2004 is insufficient to overcome the rejection of claims 1-20 based upon the references applied under 35 U.S.C. 103 as

set forth in the last Office action because the showing is not commensurate in scope with the claims. Further, In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-7, 9-13, 15-17 and 19-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of copending application 10/309,999. Although the conflicting claims are not identical, they are not

patentably distinct from each other because both applications are directed to the same carotenoid cyclodextrin complexes and methods of making such compounds.

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2). Copending application 10/309,999 teaches the compositions and methods of making the carotenoid compositions as the applicant's claims. The copending application 10/309,999 contains virtually the same compositions and methods and disclose all of the elements of the claims in the current application.

The subject matter to which claims 1-3, 5-7, 9-13, 15-17 and 19-20 are directed have been set forth in the office action dated 29 October 2004. Copending application 10/309,999

teaches all the limitations of claims 1-3, 5-7, 9-13, 15-17 and 19-20 in the current application. Copending application 10/309,999, however, does not teach the limitations of claims 1-3, 5-7, 9-13, 15-17 and 19-20 of the current application in the same format as the current application.

Claims 1-3, 5-7, 9-13, 15-17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over copending application 10/309,999. The current claims are obvious variants of the copending application. For example, applicant's claim 1 is a combination of 10/309,999 claims 1, 2 and 8 and the freeze-drying process in paragraphs 19-20; applicant's claims 2 and 12 are not distinct as to 10/309,999 claim 3 and paragraph 12; applicant's claims 3 and 13 are not distinct as to 10/309,999 paragraph 12; applicant's claims 5 and 15 are not distinct as to US 10/309,999 A1 claim 6; applicant's claims 6, 7, 16 and 17 are not distinct as to 10/309,999 claim 7 and paragraph 10; applicant's claim 11 is not distinct as to 10/309,999 claim 11 and paragraph 20; applicant's claim 12 is not distinct as to 10/309,999 claim 11 and paragraph 20 and applicant's claims 9, 10, 19 and 20 are not distinct as to 10/309,999 paragraphs 12 and 13 because soft gelatin capsules are made from gelatin as taught in paragraph 13; moreover, those that are approved by the U.S. Food and Drug Administration are for animal or human ingestion.

10/309,999 paragraph 6, 12 and 13 provide the motivation for the applicant to claim the teachings of the prior art in an attempt to optimize the cyclodextrin/carotenoid formulations for use in soft gelatin capsules. This is suggested in paragraph 6 where it is taught that carotenoid/cyclodextrin biopharmaceutic properties give rise to poor bioavailability in capsules and tablets; therefore, inherently suggesting other oral dosage forms may provide improved bioavailability. Then stating that the complex must be coated in a FDA approved coating (see paragraph 12) that consists of gelatin (see paragraph 13). As a result, those familiar with the

pharmaceutical arts would find these suggestions as a motivation to optimize a formulation for use in soft gelatin capsules.

Therefore, it would have been obvious to one having ordinary skill in this art at the time the invention was made to optimize a cyclodextrin/carotenoid complex for formulation in soft gelatin capsules having the above cited reference before him. By considering the teachings of copending application 10/309,999, one skilled in the art would have a reasonable expectation of success in reformatting the teachings of the copending application to make the claims of the current application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-10, remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Leuenberger *et al.* (US 5,221,735), Fukamachi *et al.* (US 4,929,774), Patel *et al.* (US 6,569,463), Orthoefer (US 4,125,630) and copending application 10/309,999. Claims 1-10 remain rejected because the applicant's arguments are not persuasive in addressing the rejections of the office action dated 29 October 2004. Further, by the applicant choosing to address each reference individually rather than in the manner that it was used to reject the claims does not provide a persuasive response that would obviate the rejection of record.

In addition, claim 9 is rejected upon new grounds. Claim 9 is directed to a formulation depending from claim 1 (as considered above) wherein the formulation is disposed in soft gelatin capsules.

The teachings of copending application 10/309,999 are discussed above. Copending application 10/309,999 does not teach that the formulation should be disposed of in soft gelatin capsules *per se*. However, Patel *et al.* teach that the resulting final formulation can be disposed of in soft gelatin capsules (see column 33 lines 53-54).

Therefore, it would have been obvious to one having ordinary skill in this art at the time the invention was made to prepare a formulation of a freeze-dried bioavailable cyclodextrin/carotenoid complex and vegetable oil and disposing the final formulation in a soft gelatin capsule having the above cited references before him. By considering the teaching of copending application 10/309,999 above as well as the teaching of Patel *et al.* regarding the use of soft gelatin capsules would lead one skilled in the art to have a reasonable expectation of success in combining teachings of copending application 10/309,999 with Patel *et al.* to obtain a pharmaceutically acceptable formulation incorporated into a soft gelatin capsules as the applicant has done.

Patel *et al.* provides the motivation to produce a "bioavailable carotenoid-cyclodextrin formulation for soft-gels and other encapsulation systems" because formulations utilizing hydrophobic pharmaceutical active ingredients incorporated into soft gelatin capsules can be used for improved delivery of pharmaceutical active ingredients (see US 6,569,463 abstract).

Claims 11-20 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Leuenberger *et al.* (US 5,221,735), Fukamachi *et al.* (US 4,929,774), Patel *et al.* (US 6,569,463), Orthoefer (US 4,125,630) and copending application 10/309,999. Claims 11-20 remain rejected because the applicant's arguments are not persuasive in addressing the rejections of the office action dated 29 October 2004. Further, by the applicant choosing to address each reference

individually rather than in the manner that it was used to reject the claims does not provide a persuasive response that would obviate the rejection of record.

Claims 4, 8, 14 and 18 are rejected upon new grounds. Claims 4, 8, 14 and 18 are directed to a formulation depending from claim 1, 7, 11 and 17, respectively, (as considered above) wherein the weight-to-weight ratio of lecithin to vegetable oil is 10:1 to 1:1.

Copending application 10/309,999 does not teach a formulation using a surfactant. Patel *et al.* does teach the use of a surfactant such as lecithin (see claims 1, 11 and 12).

Therefore, it would have been obvious to one having ordinary skill in this art at the time the invention was made to optimize a formulation of freeze-dried bioavailable cyclodextrin/carotenoid complex blended in vegetable oil with lecithin in a lecithin to vegetable oil range from 10:1 to 1:1 wherein the formulation is then incorporated into soft gelatin capsules having the above cited references before him. By considering the teaching of copending application 10/309,999 above as well as the teaching of Patel *et al.* regarding the use of and effective solubilizing amount of lecithin would lead one skilled in the art to have a reasonable expectation of success in combining copending application 10/309,999 and Patel *et al.* to obtain an optimized bioavailable freeze-dried cyclodextrin/carotenoid complex formulated with lecithin to inhibit the release of active ingredients or modulate the dissolution properties of the formulation as the applicant has done.

Patel *et al.* provides the motivation to produce a "bioavailable carotenoid-cyclodextrin formulation for soft-gels and other encapsulation systems" that makes use of lecithin because formulations utilizing such materials can be used for improved delivery of pharmaceutical active ingredients (see US 6,569,463 abstract).

Claim 19 is rejected on new grounds. Claim 19 is directed to a formulation depending from claim 11 (as considered above) wherein the formulation is for human ingestion.

The teachings of copending application 10/309,999 are discussed above. Copending application 10/309,999 does not teach that the formulation is for human ingestion. However, Patel *et al.* teach that the resulting final formulation is for human ingestion (see column 43 lines 62-63, claim 27 and claim 53).

Therefore, it would have been obvious to one having ordinary skill in this art at the time the invention was made to prepare a formulation of a freeze-dried bioavailable cyclodextrin/carotenoid complex blended in vegetable oil wherein the formulation is then incorporated into soft gelatin capsules for human ingestion having the above cited references before him. By considering the teachings of copending application 10/309,999 above as well as the teaching of Patel *et al.* regarding the final formulation being for human ingestion would lead one skilled in the art to have a reasonable expectation of success in combining teachings of copending application 10/309,999 with Patel *et al.* to obtain a pharmaceutically acceptable formulation for human ingestion as the applicant has done.

Patel *et al.* provides the motivation to produce a "bioavailable carotenoid-cyclodextrin formulation for soft-gels and other encapsulation systems" because formulations utilizing hydrophobic pharmaceutical active ingredients present delivery challenges due to their physiochemical properties (see US 6,569,463 abstract).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew L. Fedowitz whose telephone number is (571) 272-3105.

I f attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew L. Fedowitz, Pharm.D., J.D.
March 7, 2005

James O. Wilson
Supervisory Patent Examiner
Art Unit 1623